



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,817	03/10/2005	Paul Erik Fabricius	36731-000040/US	5433
36593 7590 01/23/2009 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195				
EXAMINER				
BUTLER, MICHAEL E				
ART UNIT		PAPER NUMBER		
3653				
MAIL DATE		DELIVERY MODE		
01/23/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/506,817

**Applicant(s)**

FABRICIUS ET AL.

**Examiner**

MICHAEL E. BUTLER

**Art Unit**

3653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 114-127 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 114-127 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action, and apply to this and any subsequent Office Actions.

#### *Priority*

1. Applicant's claim of priority as a national stage 371 application of application of **PCT/DK03/00142 International Filing Date: 03/06/2003** which claims priority to applications PA 2002 01365 filed 9/16/02 and PA 2002 00352 filed 3/7/02 both in Denmark is acknowledged.

#### *Drawings*

2. The drawings are acceptable.

#### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
- (c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claim(s) 114-115 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Eckernus et al. 5072430 which discloses all the claimed elements including:

A medication dispenser 90 for rupturable blister pack medication 91 having protrusion on one side (1 fig 3 also c4 L 60-69 the sensing contacts protrude, 110, 111, 112), patient compliance monitoring and verification, blister card indentation sensing (c5 L 11-31, does not engage with coding if no indentations).

(Re: cl 114) at least one blister card (91);

and a medical dispenser (90) removably holding the at least one blister card inserted therein, the at least one blister card holding a desired number of medical doses and having at least one indentation (96 fig 7 ), and said dispenser provides information for a user in relation to taking at least one of the desired number of medical doses, the medical dispenser including: a stationary member for introduction into the at least one indentation of the at least one blister card if the at least one blister card is fully introduced into the medical dispenser, and a first detector that detects the at least one blister card if the stationary member is introduced into the at least one indentation, such that the stationary member prevents a blister card not having an indentation from being fully introduced into the medical dispenser and being detected by the first detector (C5 L 28-31)  
(Re: cl 115)wherein the at least one blister card includes at least one selected from the group consisting of at least one additional indentation (96,96 fig 7) , a hole and a protrusion at each of a plurality of desired positions, and the medical dispenser includes a second detector that detects the at least one of the at least one additional indentation, the hole and the protrusion at each of the plurality of desired positions, and a processor that operates the medical dispenser on the basis of an output from the second detector. ( bias and surface in 80-83 bias pack and recognize inserted card; c4 L 61-67)

5. Claim(s) 114 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Simon 4660991 which discloses all the claimed elements including:

at least one blister card (2);  
and a medical dispenser (1) removably holding the at least one blister card inserted therein, the at least one blister card holding a desired number of medical doses and having at least one indentation (21), and said dispenser provides information for a user in relation to taking at least one of the desired number of medical doses, the medical dispenser including: a stationary member (33 fig 4) for introduction into the at least one indentation of the at least one blister card if the at least one blister card is fully introduced into the medical dispenser, and a first detector that detects the at least one blister card if the stationary member is introduced into the at least one indentation, such that the stationary member prevents a blister card not having an indentation from being fully introduced into the medical dispenser and being detected by the first detector (c6 L 21-35)

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim(s) 124-127 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckermas et al. 5072430 in view of Haber et al. 5405011 wherein the former discloses the elements previously discussed and further discloses:

(Re: cl 125) wherein the medical dispenser receives the at least one blister card, in the slot, in a direction along the longitudinal direction of the at least one blister card.(91 fig 7; c5 L 11-14)  
(Re: cl 126) wherein the medical dispenser has a first surface and is adapted to bias an edge portion of each blister card being received in the medical dispenser against the first surface ( bias and surface in 80-83 bias pack and recognize inserted card; c4 L 61-67)  
(Re: cl 127) wherein the detector is positioned a desired distance from the First surface and is able to detect the at least one blister card positioned between the detector and the First surface (80-83 bias pack and recognize inserted card; c4 L 61-67).

the latter discloses any elements not inherently taught by the former including:

(Re: cl 124) (114) wherein the medical dispenser holds the at least one blister card in a manner so that the at least one blister card is curved in a direction at least substantially along a longitudinal direction of the at least one blister card (P Fig 2B).

It would have been obvious at the time of the invention for Eckernis et al. use a curved blister pack to save surface area and ease of use by dexteriously challenged patients, and the ability to store additional medication in a limited space as taught by Haber et al..

8. Claim(s) 116-123 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckermas et al. 5072430 in view of Parkhurst et al. 5412372 wherein the former discloses the elements previously discussed and further discloses:

(Re: cl 116) wherein the medical dispenser monitors, from each of the plurality of desired positions of the at least one blister card where the at least one of the at least one additional indentation, the hole and the protrusion is detected ( c4 L 61-67)

(Re: cl 117) wherein the second detector has, at each of the plurality of desired positions, a mechanical switch that is displaced if the at least one of the at least one additional indentation, the hole and the protrusion exists at the desired position of the at least one blister card (bias and surface in 80-83 bias pack and recognize inserted card; (c5 L 25-31; c4 L 61-67)

(Re: cl 118) information relating to points in time when the user gains access to at least one of the desired number of medical doses (c5 L 25-31)

(Re: cl 119) identified by the presence or absence of the at least one of the at least one additional indentation, the hole and the protrusion at the plurality of desired positions of the at least one blister card (c5 L 28-31 )

a clocking device (c4 L 55)

(Re: cl 121) wherein the at least one of the at least one additional indentation, the hole and the protrusion of the at least one blister card is made subsequent to manufacture of the at least one blister card, and the medical dispenser derives the information from the at least one of at least one additional indentation, the hole and the protrusion made subsequent to manufacture of the at least one blister card (96-96, c5 L 25-28)

(Re: cl 122) wherein the medical dispenser further comprises a third detector that detects ff the user gains access to at least one of the desired number of medical doses.(c5 L 25-31)

(Re: cl 123) wherein the medical dispenser further comprises a sensor that determines if the user gains access to at least one of the desired number of medical doses.(c5 L 25-31)

the latter discloses any elements not inherently taught by the former including:

(Re: cl 116) Wherein the information on the pack comprises at least one of : a frequency of recommended intake of the desired number of medical doses, recommended points in time of intake of the desired number of medical doses, and a manner of informing the user when to take the desired number of medical doses (C3 L 20-27 )

(Re: cl 118) wherein the medical dispenser further comprises a sensor that determines a compliance of the user's intake of the desired number of medical doses based on:

a desired medication schedule identified by the presence or absence of the at least one of at least one additional indentation, the hole and the protrusion at the desired positions of the at least one blister card (c3 L 20-27),

(Re: cl 119)a desired medication schedule (C3 L 20-27)

(Re: cl 120) wherein the medical dispenser receives, from the user, information relating to at least one of: how to calculate compliance, and how to inform the user of compliance (C3 L 20-27).

It would have been obvious at the time of the invention for Eckernis et al. to place scheduling or dosing instructions on the blister card to program the dispenser in accordance with the accompanying medication as taught by Parkhurst et al..

***Response to Amendments/Arguments***

9. The amendments overcome the rejections under 35 USC 112 second paragraph.

Eckernas prevents card from being fully introduced is part of an operational condition precedent that may or may not be precedent. i.e., Is applicant asserting his device is not infringing if a device does not infringe his claims if the card is not actually introduced? Likewise, only if the stationary member is introduced into the indentation?

***Conclusion***

10. Applicant's amendment necessitated the new grounds for rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Exmr. Michael E. Butler whose telephone number is (571) 272-6937.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Mackey, can be reached on (571) 272-6916. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/M. E. B./

Examiner, Art Unit 3653

/Patrick H. Mackey/

Supervisory Patent Examiner, Art Unit 3653